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(b) *Provider of services (referred to as a provider)* has the same meaning as the term ''provider'' in §400.202 of this chapter.

(c) *Supplier* has the same meaning as the term ''supplier'' at §400.202 of this chapter.

(d) *Claim* means an itemized billing statement from a provider or supplier that, except in the context of Part D prescription drug event data, requests payment for a list of services and supplies that were furnished to a Medicare beneficiary in the Medicare fee-for-service context, or to a participant in other insurance or entitlement program contexts. In the Medicare program, claims files are available for each institutional (inpatient, outpatient, skilled nursing facility, hospice, or home health agency) and non-institutional (physician and durable medical equipment providers and suppliers) claim type as well as Medicare Part D Prescription Drug Event (PDE) data.

(e) *Standardized data extract* is a subset of Medicare claims data that the Secretary would make available to qualified entities under this subpart.

(f) *Beneficiary identifiable data* is any data that contains the beneficiary's name, Medicare Health Insurance Claim Number (HICN), or any other direct identifying factors, including, but not limited to postal address or telephone number.

(g) *Encrypted data* is any data that does not contain the beneficiary's name or any other direct identifying factors, but does include a unique CMS-assigned beneficiary identifier that allows for the linking of claims without divulging any direct identifier of the beneficiary.

(h) *Claims data from other sources* means provider- or supplier-identifiable claims data that an applicant or qualified entity has full data usage right to due to its own operations or disclosures from providers, suppliers, private payers, multi-payer databases, or other sources.

(i) *Clinical data* is registry data, chart-abstracted data, laboratory results, electronic health record information, or other information relating to the care or services furnished to patients that is not included in administrative claims data, but is available in electronic form.

§401.705 Eligibility criteria for qualified entities.

(a) *Eligibility criteria:* To be eligible to apply to receive data as a qualified entity under this subpart, an applicant generally must demonstrate expertise and sustained experience, defined as 3 or more years, in the following three areas, as applicable and appropriate to the proposed use:

(1) Organizational and governance criteria, including:

(i) Expertise in the areas of measurement that they propose to use in accurately calculating quality, and efficiency, effectiveness, or resource use measures from claims data, including the following:

(A) Identifying an appropriate method to attribute a particular patient's services to specific providers and suppliers.

(B) Ensuring the use of approaches to ensure statistical validity such as a minimum number of observations or minimum denominator for each measure.

(C) Using methods for risk-adjustment to account for variations in both case-mix and severity among providers and suppliers.

(D) Identifying methods for handling outliers.

(E) Correcting measurement errors and assessing measure reliability.

(F) Identifying appropriate peer groups of providers and suppliers for meaningful comparisons.

(ii) A plan for a business model that is projected to cover the costs of performing the required functions, including the fee for the data.

(iii) Successfully combining claims data from different payers to calculate performance reports.

(iv) Designing, and continuously improving the format of performance reports on providers and suppliers.

(v) Preparing an understandable description of the measures used to evaluate the performance of providers and suppliers so that consumers, providers and suppliers, health plans, researchers, and other stakeholders can assess performance reports.

(vi) Implementing and maintaining a process for providers and suppliers identified in a report to review the report prior to publication and providing a timely response to provider and supplier inquiries regarding requests for data, error correction, and appeals.

(vii) Establishing, maintaining, and monitoring a rigorous data privacy and security program, including disclosing to CMS any inappropriate disclosures of beneficiary identifiable information, violations of applicable federal and State privacy and security laws and regulations for the preceding 10-year period (or, if the applicant has not been in existence for 10 years, the length of time the applicant has been an organization), and any corrective actions taken to address the issues.

(viii) Accurately preparing performance reports on providers and suppliers and making performance report information available to the public in aggregate form, that is, at the provider or supplier level.

(2) Expertise in combining Medicare claims data with claims data from other sources, including demonstrating to the Secretary's satisfaction that the claims data from other sources that it intends to combine with the Medicare data received under this subpart address the methodological concerns regarding sample size and reliability that have been expressed by stakeholders regarding the calculation of performance measures from a single payer source.

(3) Expertise in establishing, documenting and implementing rigorous data privacy and security policies including enforcement mechanisms.

(b) *Source of expertise and experience:* An applicant may demonstrate expertise and experience in any or all of the areas described in paragraph (a) of this section through one of the following:

(1) Activities it has conducted directly through its own staff.

(2) Contracts with other entities if the applicant is the lead entity and includes documentation in its application of the contractual arrangements that exist between it and any other entity whose expertise and experience is relied upon in submitting the application.

§ 401.707 Operating and governance requirements for qualified entities.

A qualified entity must meet the following operating and governance requirements:

(a) Submit to CMS a list of all measures it intends to calculate and report, the geographic areas it intends to serve, and the methods of creating and disseminating reports. This list must include the following information, as applicable and appropriate to the proposed use:

(1) Name of the measure, and whether it is a standard or alternative measure.

(2) Name of the measure developer/owner.

(3) If it is an alternative measure, measure specifications, including numerator and denominator.

(4) The rationale for selecting each measure, including the relationship to existing measurement efforts and the relevancy to the population in the geographic area(s) the entity would serve, including the following:

(i) A specific description of the geographic area or areas it intends to serve.

(ii) A specific description of how each measure evaluates providers and suppliers on quality, efficiency, effectiveness, and/or resource use.

(5) A description of the methodologies it intends to use in creating reports with respect to all of the following topics:

(i) Attribution of beneficiaries to providers and/or suppliers.

(ii) Benchmarking performance data, including the following:

(A) Methods for creating peer groups.

(B) Justification of any minimum sample size determinations made.

(C) Methods for handling statistical outliers.

(iii) Risk adjustment, where appropriate.

(iv) Payment standardization, where appropriate.

(b) Submit to CMS a description of the process it would establish to allow providers and suppliers to view reports confidentially, request data, and ask for the correction of errors before the reports are made public.

(c) Submit to CMS a prototype report and a description of its plans for making the reports available to the public.